UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,111	10/22/1999	J. ROBERT MITCHELL	10991572-1	1439

22878 7590 06/03/2002

AGILENT TECHNOLOGIES, INC.
INTELLECTUAL PROPERTY ADMINISTRATION, LEGAL DEPT.
P.O. BOX 7599
M/S DL429
LOVELAND, CO 80537-0599

EXAMINER	
BEX, PATRICIA K	
ART UNIT	**PAPER NUMBER**
1743	9

DATE MAILED: 06/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

MF-9

Office Action Summary	Application No.	Applicant(s)	
	09/426,111	MITCHELL, J. ROBERT	
	Examiner	Art Unit	
	P. Kathryn Bex	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-28 and 30-47* is/are pending in the application.

4a) Of the above claim(s) *12-28, 33-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-11,30-32 and 42-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The cancellation of claims 1 and 29 and the addition of claims 45-47 in paper No. 8, is acknowledged and has been entered into the record.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2-11, 30-32, 42-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 5, now recites "a first set of multiple fluid distribution channels each disposed between the first port and the chamber". However, this recitation is *not* supported within the instant specification. Throughout the specification the multiple fluid distribution channels are explicitly disclosed as being disposed "between the first port and the multiple features of the received substrate, so as direct fluid flow between the multiple regions across the first side of the received substrate", see for example paragraph bridging pages 2-3. Same deficiency was found in claims 6, 31 and 32.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2-11, 30-32, 42-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5, now recites "a first set of multiple fluid distribution channels each disposed between the first port and the chamber". The "chamber" is defined within the claims as being formed by the substrate 10 and the housing 34. Therefore, as can be seen from Figures 4-5 the chamber can extend from the inlet port 42 to the outlet port 50, making the chamber able to house the distribution fluid channels. Therefore is not clear as to how the channels are disposed "between" the first port 42 and the "chamber".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Winkler *et al* (USP 5,384,261).

Winkler *et al* teach a method and package for performing polymer synthesis on a substrate array 401 having multiple features, i.e. linker molecules. The package comprising a housing which receives the substrate such that the housing and the substrate define a chamber. The housing including a first port 411 and first set of multiple fluid distribution channels 409

disposed between the first port 411 and the chamber (Fig. 4B). Additionally, Winkler *et al* teach adding fluid through the first port such that fluid flow is directed by the multiple fluid distribution channels between the multiple different regions across the first side of the received substrate from the first port. Moreover, Winkler *et al* teach the use of valves 608 at the end of each channel such that if reagent is delivered to the top of the substrate it will flow through the open channel only (column 7, line 31- column 12, line 17, Fig. 4A-B, 5B, 6A).

8. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (WO 96/30124).

Freeman teaches a method and package for performing polymer synthesis on a substrate array, e.g. slide or membrane (page 2, 3rd paragraph- page 3, 2nd paragraph) having multiple features, i.e. linker molecules. The package comprising a housing 82 having a chamber 86 formed by the substrate and housing, which is accessible through a first port 88. The housing includes a first set of multiple fluid distribution channels 89 disposed between the first port and the chamber. Additionally, Freeman teaches adding fluid through the first port such that fluid flow is directed by the multiple fluid distribution channels between the multiple different regions across the first side of the received substrate from the first port. Moreover, Freeman discloses wherein all of the channels are valved by a three-way valve mechanism 90 (page 16, last paragraph- page 17, 1st full paragraph, Figs.7A-B).

9. Claims 2-4, 6, 9, 30-31, 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Juncosa *et al* (USP 6,225,109).

Juncosa *et al* teach a package for performing polymer synthesis on a

substrate array 16, 140 having multiple features 50, 144. The package comprising a housing having a chamber 27, 130 formed by the housing and the substrate. The chamber is accessible through a first port 23, 134 (Figs. 2, 18). The housing including a first set of multiple fluid distribution channels 25, 142 disposed between the first port and the chamber. Additionally, Juncosa *et al* teach adding fluid through the first port such that fluid flow is directed by the multiple fluid distribution channels between the multiple different regions across the first side of the received substrate from the first port. Moreover, Juncosa *et al* disclose wherein all of the channels are micro or capillary sized, i.e. 10 microns to 5 millimeters. The substrate is then analyzed in a standard manner, i.e. fluorescence, eye, color, or laser reader. A CCD camera or PC scanner can be used to record the results. (columns 4-10). Note: it is well-known within the art that channels 10 microns in diameter exhibit capillary action to retain fluid.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler *et al* (USP 5,384,261) or Freeman (WO 96/30124) in view of Besemer *et al* (USP 6,287,850).

Winkler *et al* and Freeman are silent regarding the use of a self-sealing closure member over the first port. However, the use of a self-sealing closure member is considered conventional in the art, see Besemer. Besemer *et al* teach a method and apparatus for directing fluid sample across a nucleic array for promoting hybridization between a target in the fluid sample and probes on the array. The device of Besemer uses an inlet port in which a self-sealing septum is seated (Fig. 7). This insures that the seal is maintained even after the fluid is injected into the cavity since the pressure immediately forces the septum to reseal itself after the needle or other fluid injecting means is removed from the port. Thus an efficient and economical seal for retaining fluid in the cavity is provided.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the system of Winkler *et al* or Freeman, the self-sealing septum, as taught by Besemer *et al* . Such a sealing means provides an efficient and economical seal for retaining fluid in the cavity (column 8, line 63- column 9, line 2).

13. Claims 7-8, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler *et al* (USP 5,384,261) or Freeman (WO 96/30124) in view of Jun *et al* (Valveless Pumping using Tranversing Vapor Bubbles in Microchannels).

Winkler *et al* and Freeman as previously discussed above, do teach the use of valves to regulate the flow of fluid within the distribution channels. However, they do not disclose the specific use of a bubble formation device comprising a bubble nucleating resistor. Jun *et al*

teach the formation of a stationary bubble formed by boiling, via a heater, a liquid flowing through a micro-channel to serve as an obstruction against flow in the channel and therefore function as a valve (Introduction and Theory sections, Fig. 1).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the system of Winkler *et al* or Freeman the bubble forming device, as taught by Jun *et al* . Valves often leak with use and affect long term reliability. In addition, valve are often formed of delicate components that must be carefully manufactured and installed for reliability. A bubble forming device requires no micro-mechanical moving parts, therefore reducing the need for valve components (abstract, introduction sections).

14. Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable Juncosa *et al* (USP 6,225,109) in view of Katoot *et al* (USP 6,184,030).

Juncosa *et al* are silent regarding the step of communicating the result of the analysis to a location remote from the location of testing. However, communicating results obtained from analysis to a remote location is considered conventional in the art, see Katoot *et al* . Katoot *et al* teach a method using polymer films arranged in a matrix to provide the ability to perform multiple analyte determinations in a single sample. The data from the membranes may be displayed, printed, stored in a data storage means, input into a computer, sent to a remote data storage means or computer, or input into a trained neural network. Additionally, the system of Katoot *et al* may be configured to transmit the data to a remote location such as the office of a health care provider, health maintenance organization, etc (column 5 , line 56- column 6, line 3).

This would aid the health care providers to evaluate data obtained from the patient samples and a form a diagnoses, prognoses, and develop a therapeutic strategy.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the system of Juncosa *et al* , communication means, as taught by Katoot *et al* , in order to aid health care providers to evaluate data obtained from the patient samples and a form a diagnoses, prognoses, and develop a therapeutic strategy (column 12, lines 10-24).

15. Claim 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler *et al* (USP 5,384,261) or Freeman (WO 96/30124) in view of Jun *et al* (Valveless Pumping using Tranversing Vapor Bubbles in Microchannels) as applied to claim 32 above, and further in view of Katoot *et al* (USP 6,184,030).

Winkler *et al* and Freeman and Jun *et al* are silent regarding the step of communicating the result of the analysis to a location remote from the location of testing. However, communicating results obtained from analysis to a remote location is considered conventional in the art, see Katoot *et al.* Katoot *et al* teach a method using polymer films arranged in a matrix to provide the ability to perform multiple analyte determinations in a single sample. The data from the membranes may be displayed, printed, stored in a data storage means, input into a computer, sent to a remote data storage means or computer, or input into a trained neural network. Additionally, the system of Katoot *et al* may be configured to transmit the data to a remote location such as the office of a health care provider, health maintenance organization, etc (column 5 , line 56- column 6, line 3). This would aid the health care providers to evaluate data

obtained from the patient samples and a form a diagnoses, prognoses, and develop a therapeutic strategy.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the system of Winkler *et al* or Freeman, and Jun *et al* communication means, as taught by Katoot *et al* , for the reasons previously set forth above.

Response to Arguments

16. Applicant's arguments filed March 28, 2002 have been fully considered but they are not persuasive. The previous rejection of claims 1-4, 29-30, 42 under 35 U.S.C. 102(b) as being anticipated by Muller *et al* (USP 5,273,905) is withdrawn since Muller *et al* do not disclose at least some of the fluid distribution channels which are valved. Applicant argues that no substantive amendment was made to claims 5, 6, 31-32, but only further clarifies the claims. Examiner does not agree. This new limitation recited in claims, did not appear in specification or claims as originally filed and therefore introduce new concepts into the disclosure. Moreover, the "chamber" is defined within the claims as being formed by the substrate 10 and the housing 34. Therefore, as can be seen from Figures 4-5 of the instant application, the chamber can extend from the inlet port 42 to the outlet port 50, making the chamber able to house the distribution fluid channels. Therefore, is not clear as to how the channels are "disposed" between the first port 42 and the chamber.

With respect to the previous rejection of claims 1-5, 29-30, 42 under 35 U.S.C. 102(b) as being anticipated by Winkler *et al* (USP 5,384,261), Applicant merely states that the channels of Winkler *et al* are not disposed between the first port and the same chamber. However, it can be clearly seen that the chamber formed between the substrate 401 and the housing elements 407

and has channels 409 disposed between the inlet 411 and the chamber (Fig. 4B). Similarly, in response to the previous rejection of claims 1-6, 9, 29-31, 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Juncosa *et al* (USP 6,225,109), Applicant states that the channels of Juncosa *et al* are individual channels and are not disposed between the first and the "same chamber" of the received substrate. Examiner does not agree, since Juncosa *et al* clearly shows the distribution channels 25 formed between the inlet 23 and the chamber 27, wherein the chambers is formed by housing 17 and assay substrate 16 (Fig. 2). The argument that the channels are not disposed between the first port and the "same" chamber is not germane to the issue since Applicant has not excluded such a feature (i.e. multiple chambers) from the claim.

In response to the previous rejection of claims 1-5, 9, 29-30, 42 under 35 U.S.C. 102(b) as being anticipated by Freeman (WO 96/30124). Applicant contends that Freeman do not teach channels that are "valved". Examiner does not agree, since Freeman shows the all the distribution channels being are valved by element 90. This element can be opened or closed (page 16, last paragraph- page 17, 1st full paragraph, Figs.7A-B).

With respect to the previous rejection of claims 7-8 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler *et al* (USP 5,384,261) or Freeman (WO 96/30124) in view of Jun *et al* (Valveless Pumping using Tranversing Vapor Bubbles in Microchannels), Applicant argues that there is no motivation for combining Freeman with the bubble system of Jun *et al*. However, as previously pointed out, Jun *et al* is relied upon for the motivation and does disclose the advantage for using a bubble forming device, since this type of valve requires no micro-mechanical moving parts, therefore reducing the need for valve components (abstract, introduction sections, Jun *et al*).

Conclusion

17. No claims allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-

7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex

P. Kathryn Bex
Patent Examiner
AU 1743
May 29, 2002

Jill Warden
Supervisory Patent Examiner
Technology Center 1700